

# GMTA/DITTA Workshop on Reliance

- **Scene Setting:** What is reliance and why is it important?
- **Session 1:** Reliance in a premarket setting
- **Session 2:** Reliance in a post market setting
- **Next Steps**



**DITTA**  
GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT &  
RADIATION THERAPY  
TRADE ASSOCIATION



**Global Medical  
Technology Alliance**  
*Innovating for a Healthier World*





# Anvisa - Brazil Post Market Experience

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**IMDRF** International Medical Device  
Regulators Forum

# ★ Reliance Activities and Anvisa Strategic Priority Plan 2024-2029

- **Anvisa Strategic Priority Plan 2024-2029**

Objective 5: To be recognized as an International Reference Regulatory Authority.

Consolidation of Anvisa leading role in the international scenario, ensuring high standards in all regulatory operations.



# Reliance Activities in Inspections

- **Pathways for the grant of GMP Certificates issued by Anvisa**

1. GMP Inspection conducted by Anvisa inspectors with the issuance of an Inspection Report attesting if the company has a Quality Management System and complies with the Good Manufacturing Practices.
2. Based on the information from other Inspection Reports issued by recognized authorities accompanied by a Risk Analysis.
3. Based on MDSAP Inspection Reports and Certificates.

Reference Legislation: RDC 687/2022



# Reliance Activities in Inspections and Resources

## CPROD – Coordination for Inspections and Law Enforcement for Medical Devices

Inspections/audits of companies

GMP Certification using risk analysis +  
reliance mechanisms and Anvisa  
Inspection Reports.

Investigation of complaints/quality defects and law  
enforcement actions

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# GMP Certification in Numbers

YEAR	GMP Certificates Issued Based on MDSAP Reports by CAUPS (total and % of total)	GMP Certificates Issued Based on Anvisa Inspection + risk matrix by CPROD	Total International GMP Certificates issued
2017	38 (4.7%)	770 (95.3%)	808
2018	107 (19.3%)	447 (80.7%)	554
2019	374 (48.7%)	394 (52.3%)	768
2020	544 (49.1%)	564 (50.9%)	1108
2021	529 (51.4%)	500 (48.6%)	1029
2022	621 (59.7%)	419 (40.3%)	1040
2023	659 (59.1%)	456 (40.9%)	1115

# Other Post Market Activities

- **Resources allocated to other activities**

- Increased number of Post Market Compliance (PMC) Inspections.
  - 85 inspections in the last 4 years \* (\*pandemic)
  - Previously approx. 4 inspections per year.
- Increased activities upon the receipt of MDSAP 5-day notice
  - 20 MDSAP 5-day notices – all were assessed, and investigations were conducted:
    - 9 immediate enforcement actions, for example: prohibition of importation;
    - 11 technical complaints confirmed;
    - 01 penalty applied.



# Other Activities

- **Resources allocated to other activities**

- Investigation of Complaints related to Quality Defects;
  - More than 1600 investigations in the last 4 years\*  
(\*pandemic)
- Launch of Monitoring Programs focused on specific products – laboratory testing.
  - COVID19 diagnosis tests
  - Needles and Syringes
  - Infusion sets





# Monitoring Programs

- **COVID19 diagnosis tests (closed January 2023)**

- 536 laboratory tests conducted
- 64.9% approved
- 35.1% not approved

- **Needles and Syringes (started August 2023)**

- 21 lab tests conducted
- 100% approved

- **Infusion sets (started September 2023)**

- 15 lab tests conducted
- 66.7 % approved
- 33.3 % not approved

data obtained on 29 February 2023



# Monitoring Programs



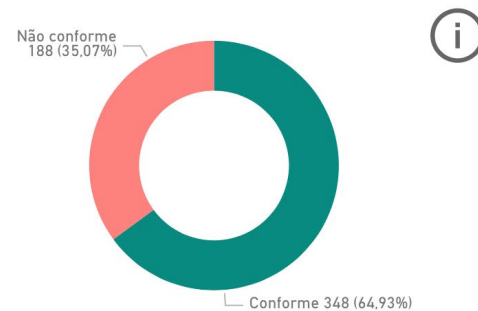
## Monitoramento pós-mercado da qualidade de dispositivos para diagnóstico *in vitro* da COVID-19: análises laboratoriais



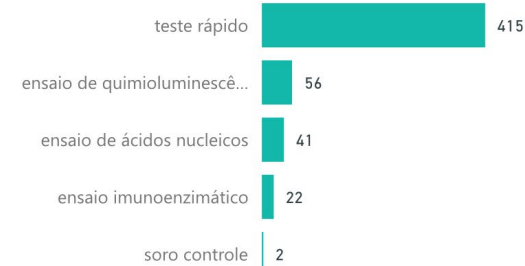
CNPJ responsável pela importação

Fabricante

### Resultados obtidos



### Amostras analisadas



536

Amostras

### Outras ações



Data do laudo	Nome comercial	Fabricante	Lote	Laudo	Avaliação (quando o resultador for "não conforme", é identificado o responsável pela importação)	Responsável pela importação (produtos não conformes)	Resoluções (clique no link)
17/08/2020	COVID-19 IgG/IgM BIO	QUIBASA QUÍMICA BÁSICA LTDA.	0012	2354.1P0/2020	Ações de fiscalização: Inutilização Suspensão - Comercialização, Distribuição - Quibasa Química Básica Ltda - 19.400.787/0001-07	Quibasa Química Básica Ltda	<a href="#">🔗</a>
17/08/2020	COVID-19 IgG/IgM BIO	QUIBASA QUÍMICA BÁSICA LTDA.	0012	2354.1P0/2020	Ações de fiscalização: Revogação de Medida Preventiva Ações de fiscalização revogadas: Interdição cautelar - Quibasa Química Básica Ltda - 19.400.787/0001-07	Quibasa Química Básica Ltda	<a href="#">🔗</a>
06/04/2020	SARS-CoV-2 Antibody Test (Lateral Flow Method),	GUANGZHOU WONDFO BIOTECH CO. LTD	W19500335	1082.1P1/2020	Conforme		--
07/04/2020	SARS-CoV-2 ANTIBODY TEST (LATERAL FLOW METHOD)	GUANGZHOU WONDFO BIOTECH CO. LTD	W19500329	1124.1P0/2020	Conforme		--
08/04/2020	2019-nCoV IgG (CLIA)	SHENZHEN NEW INDUSTRIES BIOMEDICAL ENGINEERING CO. LTD	271200020	1084.1P0/2020	Conforme		--

Data da última atualização: 29/02/2024

# Anvisa Silver Jubilee Celebration



**The Agency  
celebrates 25  
years of  
contributions to  
public health and  
to the quality of  
life of Brazilian  
citizens**



**IMDRF**

International Medical Device  
Regulators Forum



United States  
of America

2024